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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Gentamicin Sulfate Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for use of gentamicin sulfate injection in the neck of 1 to 3-day-old turkey poults for prevention of early mortality due to susceptible *Arizona paracolon* infections.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, filed supplemental NADA 200-147 that provides for subcutaneous use of Gents-Ject® (gentamicin sulfate) injectable solution in the neck of 1 to 3-day-old turkey poults as an aid in the prevention of early mortality due to *A. paracolon* infections susceptible to gentamicin. The supplemental NADA is approved as of October 30, 1998, and the regulations are amended in 21 CFR 522.1044(b)(4) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11 (e)(2) (ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1044 is amended by revising paragraph (b)(4) to read as follows:

§ 522.1044 Gentamicin sulfate injection.

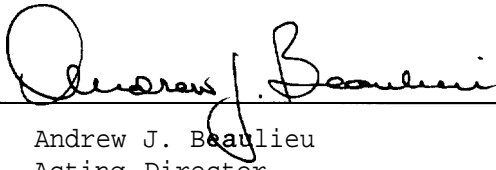
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(b) * * *

(4) See No. 050604 for use of 100 milligram-per-milliliter solution in turkeys as in paragraph (d)(2) of this section and in chickens as in paragraph (d)(3) of this section.

* * * * *

Dated: Dec. 2, 1998
December 2, "1998



Andrew J. Beaulieu
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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